

REMARKS

Allowed Claims

As set forth on page 3 of the Office Action, claims 15-23, 39-52, 54, 55, 65, 67 and 71 have been allowed.

Claim Rejections – 35 USC §102 and 103

Claims 53, 63, 64, 66 and 68-70 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,042,582 to Ray (hereafter “the ‘582 reference”). Claims 63, 64, 66 and 68-70 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,601,556 to Pisharodi (hereafter “the ‘556 reference”). Although dependent claim 65 was also indicated as being rejected in view of each of these references, the Applicant presumes this was an oversight since claim 65 depends from allowed independent base claim 67.

Independent Claim 53

Independent claim 53 was rejected as being anticipated by the ‘582 reference to Ray. With regard to the ‘582 reference, even assuming arguendo that the insertion end portion 26 comprises an axial stem portion, and that the trailing end portion 24 comprises a transverse flange portion, there is no teaching that the retractor tube 100 is in any way “selectively and releasably engaged” with the stem portion, as originally recited in independent claim 53.

As set forth on page 4 of the Office Action, “[r]egarding the word ‘engaged’ the Examiner has interpreted the word broadly, therefore, the stem portion and the surgical instrument engage to each other.” However, even under a broad interpretation of the word “engaged”, the ‘582 reference fails to teach or even suggest that the retractor tube 100 is in any way engaged to the insertion end portion 26 of the spacer 14. As shown in Figure 6 of the ‘582 reference, the retractor tube 100 does not even contact the spacer 14, much less engage the spacer 14 in a selective and releasable manner. To the contrary, as discussed throughout the written description, the spacer 14 is inserted into a first lateral side portion of the intervertebral space (col. 6, ll. 57-62), with the retractor tube 100 inserted into a second later side portion of the

intervertebral space (col. 7, ll. 14-16). Following preparation of the adjacent vertebrae for receipt of an implant 500, the spacer 14 is removed and the retractor 100 is inserted into the portion of the intervertebral space previously occupied by the spacer 14 (col. 8, ll. 30-38). During the entire surgical procedure, the retractor tube 100 does not come into contact with the spacer 14 in any manner that could be said to selectively and releasably engage the retractor tube 100 to the spacer 14.

On page 3 of the Office Action, it is also stated that “[e]xpressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim.” However, the Applicant submits that recitation that the tubular sleeve is “selectively and releasably engaged” with the stem portion is directed to a defined structural relationship between the tubular sleeve and the stem portion, and is not merely directed to an intended operation of the claimed device. Nevertheless, the Applicant has amended independent claim 53 to recite “said tubular sleeve and said stem portion configured to provide selective and releasable engagement therebetween”. As discussed above, the ‘582 reference fails to teach or even suggest that the retractor tube 100 is in any way engaged to the insertion end portion 26 of the spacer 14, much less configured to provide selective and releasable engagement between the retractor tube 100 and the spacer 14.

For at least the forgoing reasons, the Applicant submits that independent claim 53 is patentable over the ‘582 reference to Ray. Accordingly, withdrawal of the rejection of independent claim 53 is respectfully requested. Additionally, the Applicant has added a new claim 72 that depends from independent claim 53 which recites further structural features associated with the selective and releasable engagement between the tubular sleeve and the stem portion. Specifically, dependent claim 72 recites that one of the stem portion and the tubular sleeve defines a passage, and another of the stem portion and the tubular sleeve defines a projection at least partially received within the passage to locate the tubular sleeve relative to the adjacent vertebrae. New claim 72 is similar to allowed dependent claim 52, and is patentable for at least the reasons supporting the patentability of independent base claim 53.

Independent Claim 63 and Dependent Claims 64, 66 and 68-70

With regard to the '582 reference to Ray, even assuming arguendo that the insertion end portion 26 comprises an axial stem portion and the trailing end portion 24 comprises a transverse flange portion, there is no teaching that the disclosed device is used "to reduce a spondylolisthesis condition between the adjacent vertebrae", as recited in independent claim 63. Specifically, the '582 reference fails to teach or even suggest the steps of engaging the trailing end portion 24 against one of the adjacent vertebrae and applying an axial force to the device "thereby resulting in axial displacement of the one of the adjacent vertebrae relative to the other of the adjacent vertebrae to reduce a spondylolisthesis condition between the adjacent vertebrae." Albeit that the trailing end portion 24 of the device appears to abut a vertebrae (see Figure 5), there is no teaching or suggestion whatsoever that an axial force is applied to the device which results in relative axial displacement between the adjacent vertebrae to reduce a spondylolisthesis condition.

On page 3 of the Office Action, it is stated that "surface 36 of flange 24 [] is *capable* of applying an axial force to the walls of the vertebrae" (emphasis added). However, the Applicant submits that independent claim 63 is a method claim that specifically recites the steps of engaging the transverse flange portion against one of the adjacent vertebrae and applying an axial force to the device to axially displace of the one of the adjacent vertebrae relative to the other of the adjacent vertebrae to reduce a spondylolisthesis condition. Albeit that the device disclosed in the '582 reference may arguably be capable of performing these recited steps, the steps themselves are neither disclosed nor suggested in the independent method claim 63. In contrast to apparatus claims which are sometimes rejected based on an assertion that the claimed device is capable of satisfying a claim limitation, this is not the case with regard to method claims recite specific steps. With regard to method claims, a prior art rejection is only warranted if the recited steps are disclosed or rendered obvious by the asserted reference. Indeed, it is not enough for the disclosed device or structure to merely be *capable* of performing the recited steps.

If the rejection of independent claim 63 based on the '582 reference is maintained, the Applicant respectfully requests an explanation as to how the '582 reference teaches the step of displacing one vertebrae relative to another vertebrae so as to reduce a spondylolisthesis

condition by engaging a transverse flange against one of the vertebrae and applying an axial force thereto. For at least the foregoing reasons, rewritten independent claim 63 is submitted to be patentable over the '582 reference to Ray.

With regard to the '556 reference to Pisharodi, although this reference discloses an apparatus for reducing a spondylolisthesis reduction, the disclosed apparatus is not configured like the device recited in rewritten independent claim 63, and clearly does not satisfy all of the steps recited in independent claim 63. As illustrated in Figure 7 of the '556 reference, the reduction apparatus includes an end portion 12 that is split longitudinally into two side-by-side members 13, 14, one of which is movable relative to the other, and with each member 13, 14 including teeth 38 (Figure 1) for gripping the endplates of the adjacent vertebrae 33, 37. The members 13, 14 are inserted into the disc space between two misaligned vertebrae 33, 37 and one of the members 14 is moved relative to the other member 13 to reposition the adjacent vertebrae 33, 37 into alignment with one another.

With regard to the reduction device disclosed in the '556 reference, all of the correction force applied to the adjacent vertebrae 33, 37 is exerted via engagement of the teeth 38 against the vertebral endplates. Notably, the reduction device fails to disclose "a transverse flange portion", as recited in rewritten independent claim 63, and clearly fails to teach or suggest the recited step of "engaging the transverse flange portion against one of the adjacent vertebrae" to reduce a spondylolisthesis condition. The reduction device illustrated and described in the '556 reference is therefore configured significantly different from the device recited in rewritten independent claim 63, and also operates and functions in a significantly different manner than that recited in independent claim 63. Nevertheless, the Applicant has amended independent claim 63 to recite the step of "engaging the transverse flange portion against an extradiscal surface of one of the adjacent vertebrae". It is well known in the field of art that the term "extradiscal" means outside of the intervertebral disc space. Also, the specification and drawing figures clearly convey that the transverse flange is engaged against an extradiscal surface of one of the adjacent vertebrae. However, as illustrated in Figure 7 of the '556 patent, no portion of the instrument engages an extradiscal surface of either of the adjacent vertebrae, as recited in independent claim 63.

For at least these reasons, independent claim 63 is submitted to be patentable over the '556 reference to Pisharodi. Accordingly, withdrawal of the rejection of independent claim 63 is respectfully requested. Claims 64, 66 and 68-70 depend from independent claim 63 and are patentable for at least the reasons supporting the patentability of independent base claim 63.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the Applicant's application is now in condition for allowance with pending claims 15-23, 39-55 and 63-72.

Reconsideration of the subject application is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

By: 

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